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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,024	12/30/2005	Dan Akerfeldt	030481-0251	3920
22428	7590	09/28/2007		
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER BLATT, ERIC D	
			ART UNIT 3709	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/563,024

Applicant(s)

GARY

Examiner

Eric Blatt

Art Unit

3709

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

KHOI H. TRAN  
SUPERVISORY PATENT EXAMINER

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12-30-2005.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

Acknowledgement is made that the present application is a national stage entry of PCT/SE04/00938 filed on June 15, 2004 which claims priority from Provisional Application 60/484310 filed July 3, 2003.

### ***Response to Amendment***

Acknowledgement is made of the Preliminary Amendment filed December 30, 2005 amending claims 10-14 and 17 adding new claim 18.

### ***Claim Objections***

Claim 7 is objected to because of the following informalities: claim 7 recites "the plug" without proper antecedent basis. For present purposes of examination, claim 7 will be interpreted to read, "The device (21) according to claim 5, characterized in that the sealing element is in the form of a plug and the plug (22) comprises a haemostatic material." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 5, and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (WO 00/78226) in view of Van Tassel et al. (US 6,949,113).

Regarding claim 1, Akerfeldt discloses a device (Figures 1-2) for sealing a puncture in a vessel, comprising:

- a sealing element 2 configured to be placed against a wall of the vessel and to seal the puncture in the vessel by contacting the vessel wall
- an elongated member 6 connected to the sealing element and configured to extend in an incision canal leading to the puncture in the vessel
- the sealing element being adapted to be positioned against an inner surface of the vessel wall
- a locking element 3 connected to the elongated member and adapted to be positioned against an outer surface of the vessel wall; and
- the sealing element being in the form of a plug

Akerfeldt does not disclose:

- the elongated member comprises a haemostatic material
- the plug comprises a haemostatic material; and
- the locking element comprises a haemostatic material.

- the elongated member having a diameter that is small, less than 25%, preferably less than 10%, in comparison to the diameter of the sealing element

Van Trussel discloses that it is old and well known to have closure devices designed to seal blood vessel walls comprise a haemostatic material. (Column 12, Lines 21-23) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by having the elongated member, the plug, and the locking element comprise a haemostatic material for purposes such as encouraging blood to coagulate, thereby preventing the vessel from leaking.

Further, It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dimensions of the elongated member and the sealing element since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 8 and 9, Akerfeldt discloses a device and a method (Figures 1-2) for sealing a puncture in a vessel, comprising:

- a sealing element 51 configured to be placed against an inner surface of a wall of the vessel and to seal the puncture in the vessel by contacting the vessel wall
- an elongated member 7, 8 connected to the sealing element and configured to extend in an incision canal leading to the puncture in the vessel
- a second sealing element which is adapted to be positioned against an outer surface of the vessel wall and is provided with saw-teeth that fit into

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corresponding recesses provided on a portion of the elongated member that extends through the second sealing element (Figure 2)

Akerfeldt does not disclose:

- the elongated member comprises a haemostatic material; and
- the second sealing element comprises a haemostatic material
- the elongated member having a diameter that is small, less than 25%, preferably less than 10%, in comparison to the diameter of the sealing element

Van Trussel discloses that it is old and well known to have closure devices designed to seal blood vessel walls comprise a haemostatic material. (Column 12, Lines 21-23) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by having the elongated member and the second sealing element comprise a haemostatic material for purposes such as encouraging blood to coagulate, thereby preventing the vessel from leaking.

Further, It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dimensions of the elongated member and the sealing element since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 1-3, 6, and 8-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (WO 00/78226) in view of Torgerson et al. (US 6,361,551).

Regarding claims 1-3, 6, and 10-18, Akerfeldt discloses a device and a method (Figures 1-2) for sealing a puncture in a vessel, comprising:

- a sealing element 2 configured to be placed against a wall of the vessel and to seal the puncture in the vessel by contacting the vessel wall
- an elongated member 6 connected to the sealing element and configured to extend in an incision canal leading to the puncture in the vessel
- the elongated member at least partly is in the form of a suture, filament or multifilament
- the sealing element is adapted to be positioned against an inner surface of the vessel wall and is held in place by the elongated member

Akerfeldt does not disclose:

- the elongated member having a diameter that is small, less than 25%, preferably less than 10%, in comparison to the diameter of the sealing element
- the elongated member comprises a haemostatic material
- the haemostatic material is a core of the elongated member
- the elongated member is coated with the haemostatic material
- the elongated member is impregnated or soaked with the haemostatic material
- the elongated member is a multifilament comprising several filaments, each of which is coated with the haemostatic material
- the haemostatic material is selected from the group comprising collagen, chitin and chitosan, thrombin, gelatine, oxidized regenerated cellulose, aprotinin,

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tranexamic acid, aminocaproic acid, desmopressin, vitamin K, factor VIII, factor V, vasopressin, and conjugated oestrogen, or combinations thereof.

Torgerson discloses a fiber (elongated member) wherein:

- the elongated member comprises a haemostatic material (Columns 1-3)
- the haemostatic material is a core of the elongated member (the whole fiber is haemostatic material, thus the core is haemostatic material)
- the elongated member is coated with the haemostatic material (Columns 1-3)
- the elongated member is impregnated or soaked with the haemostatic material (Columns 1-3)
- the elongated member is a multifilament comprising several filaments, each of which is coated with the haemostatic material (Columns 1-3, Column 13, Lines 14-15)
- the haemostatic material is collagen

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by substituting the fiber disclosed in Torgerson for the elongated member 10 for purposes such as encouraging blood to coagulate, thereby preventing the vessel wall from leaking. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dimensions of the elongated member and the sealing element since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.



Regarding claim 6, Akerfeldt discloses a device (Figures 1-2) for sealing a puncture in a vessel, comprising:

- a sealing element 3 configured to be placed against a wall of the vessel and to seal the puncture in the vessel by contacting the vessel wall
- an elongated member 8 connected to the sealing element and configured to extend in an incision canal leading to the puncture in the vessel
- the sealing element is in the form of plug, which is adapted to be positioned against an outer surface of the vessel wall; and
- an anchor member 2 connected to the elongated member and adapted to be positioned against an inner surface of the vessel wall

Akerfeldt does not disclose:

- the elongated member comprises a haemostatic material
- the elongated member having a diameter that is small, less than 25%, preferably less than 10%, in comparison to the diameter of the sealing element

Torgerson discloses a fiber (elongated member) wherein:

- the elongated member comprises a haemostatic material (Columns 1-3).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Akerfeldt by substituting the fiber disclosed in Torgerson for the elongated member 10 for purposes such as encouraging blood to coagulate, thereby preventing the vessel wall from leaking. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the

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dimensions of the elongated member and the sealing element since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571) 272-9735. The examiner can normally be reached on Monday to Friday, 7:30 A.M. to 5:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Khoi Tran can be reached on (571) 272-6919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9/25/2007  
EB

KHOI H. TRAN  
SUPERVISORY PATENT EXAMINER  
